

AMENDATORY SECTION (Amending Order 274, filed 5/26/92, effective 6/26/92)

WAC 246-310-261 ((Open)) Adult heart surgery standards and need forecasting method. (1) ((Open)) Heart surgery means a specialized surgical procedure of the heart and great vessels in the chest (excluding organ transplantation) ((which utilizes a heart-lung bypass machine and is intended to correct congenital and acquired cardiac and coronary artery disease)).

(2) ((Open)) Heart surgery is a tertiary service as listed in WAC 246-310-020. To be granted a certificate of need, ((an open)) a heart surgery program ((shall)) must meet the standards in this section in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240. To be granted a certificate of need for adult heart surgery, a hospital is also required to have or concurrently obtain a separate certificate of need for adult elective coronary intervention as defined in WAC 246-310-262.

(3) The department shall review new adult heart surgery applications using the concurrent review cycle in this subsection.

(a) Applicants must submit letters of intent between the first working day and last working day of July of each year.

(b) Initial applications must be submitted between the first working day and last working day of August of each year.

(c) The department shall screen initial applications for completeness by the last working day of September of each year.

(d) Responses to screening questions must be submitted by the last working day of October of each year.

(e) The public review and comment period for applications begins on November 16 of each year. If November 16 is not a working day in any year, then the public review and comment period begins on the first working day after November 16.

(f) The public comment period is limited to ninety days, unless extended under WAC 246-310-120 (2)(d). The first sixty days of the public comment period shall be reserved for receiving public comments and conducting a public hearing, if requested. The remaining thirty days shall be for the applicant or applicants to provide rebuttal statements to written or oral statements submitted during the first sixty-day period. Any interested person that:

(i) Is located or resides within the applicant's health service area;
(ii) Testified or submitted evidence at a public hearing; and
(iii) Requested in writing to be informed of the department's decision,
must also be provided the opportunity to provide rebuttal statements to written or oral statements submitted during the first sixty-day period.

(g) The final review period may not exceed sixty days, unless extended under WAC 246-310-120 (2)(d).

(4) The department may convert the review of an application that was initially submitted under the concurrent review cycle to a regular review process if the department determines that the application does not compete with another application.

(5) Any letter of intent or certificate of need application submitted for review in advance of this schedule, or certificate of need application under review as of the effective date of this section, shall be held by the department for review according to the schedule in this section.

(6) Standards.

(a) A minimum of two hundred fifty ((open)) heart surgery procedures

per year (~~((shall))~~) must be performed at (~~((institutions))~~) hospitals with an (~~((open))~~) adult heart surgery program by the third year of operation and for each year thereafter.

(b) Hospitals applying for a certificate of need (~~((shall))~~) must demonstrate that they can meet one hundred ten percent of the minimum volume standard. (~~((To do so,))~~) The applicant hospital must provide (~~((written documentation, which is verifiable, of open heart surgeries performed on patients referred by active medical staff of the hospital. The volume of surgeries counted must be appropriate for the proposed program (i.e., pediatric and recognized complicated cases would be excluded).))~~).

~~((c) No new program shall be established which will reduce an existing program below the minimum volume standard.~~

~~((d) Open heart surgery programs shall have at least two board certified cardiac surgeons, one of whom shall be available for emergency surgery twenty-four hours a day. The practice of these surgeons shall be concentrated in a single institution and arranged so that each surgeon performs a minimum of one hundred twenty-five open heart surgery procedures per year at that institution.~~

~~((e) Institutions with open heart surgery programs shall have plans for facilitating emergency access to open heart surgery services at all times for the population they serve. These plans should, at minimum, include arrangements for addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.), and the maintenance of or affiliation with emergency transportation services (including contingency plans for poor weather and known traffic congestion problems).~~

~~((f))~~) data from CHARS demonstrating:

(i) The zip codes served by the applying hospital;

(ii) The applying hospital's percentage of total adult hospital admissions in the applicable zip codes during the most recent available three years data. Expired patients will not be counted;

(iii) The number of heart surgeries performed on patients from these zip codes during the most recent available three years data. The percentage established in (ii) of this subsection must then be applied to the number of heart surgeries. This number must be equal to or greater than two hundred seventy-five (one hundred ten percent of the minimum volume).

(c) The department shall not grant a certificate of need to a new program if the new program would:

(i) Cause the number of procedures at any existing program to drop below two hundred seventy-five procedures per year; or

(ii) Reduce the number of procedures at any existing program that has not yet reached two hundred seventy-five procedures per year.

(d) At the time of project commencement, and thereafter, heart surgery programs must have at least two cardiac surgeons. Of the two required surgeons, one must be the program's designated head and be a U.S. board certified cardiac or cardio-thoracic surgeon. The other required surgeon must be a U.S. board certified or board prepared cardiac or cardio-thoracic surgeon. Board prepared status must not extend beyond five years.

(e) Each required surgeon must perform a minimum of one hundred twenty-five heart surgery procedures per year. By the end of the third year of the program's operation each required surgeon must perform at least one hundred heart surgery procedures at the applying hospital.

(f) The program must provide twenty-four hour coverage.

(g) Hospitals with heart surgery programs must have plans for facilitating emergency access to heart surgery services at all times for the population they serve. These plans should, at minimum, include arrangements for addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.), and the maintenance of or affiliation with emergency transportation services

(including contingency plans for poor weather and known traffic congestion).

(h) Hospitals with heart surgery programs must provide a copy of the hospital's QI plan that includes/incorporates a section specific to the heart surgery program.

(i) When a certificate of need is issued, it will be conditioned, at a minimum, to require ongoing compliance with the certificate of need standards. Failure to operate the heart surgery program in accordance with certificate of need standards may be grounds for revocation or suspension of a hospital's certificate of need, or other appropriate licensing or certification action.

(j) In the event two or more hospitals are competing to meet the same forecasted net need, the department shall consider the following factors when determining which proposal best meets forecasted need:

- (i) The most appropriate improvement in geographic access;
- (ii) The most cost efficient service;
- (iii) Minimizing impact on existing programs;
- (iv) Providing the greatest breadth and depth of cardiovascular and support services; and
- (v) Facilitating emergency access to care.

~~((g))~~ (k) Hospitals granted a certificate of need have three years from the date ((the program is initiated)) of project commencement to ((establish)) meet the program ((and meet these)) procedure volume standards.

~~((h))~~ (l) These standards should be reevaluated ((in at least)) every three years.

~~((4) Steps in the need forecasting method. The department will develop a forecast of need for open heart surgery every year using the following procedures.~~

~~(a) Step 1. Based upon the most recent three years volumes reported for the hospitals within each planning area, compute the planning area's current capacity and the percent of out-of-state use of the area's hospitals. In those planning areas where a new program is being established, the assumed volume of that institution will be the greater of either the minimum volume standard or the estimated volume described in the approved application and adjusted by the department in the course of review and approval.~~

~~(b) Step 2. Patient origin adjust the three years of open heart surgery data, and compute each planning area's age-specific use rates and market shares.~~

~~(c) Step 3.)~~ (7) Need forecasting method. The data used for evaluating applications submitted during the concurrent review cycle will be the most recent three years CHARS data available at the close of the application submittal period for that review cycle.

(a) Step 1. Compute each planning area's current capacity. In those planning areas where a new program is being established, the assumed volume of that hospital will be the greater of the actual volume or the minimum volume standard or the estimated volume described in the approved application, including any adjustments made by the department in the course of review and approval.

(b) Step 2. Compute the average percent of out-of-state use of each planning area.

(c) Step 3. Adjust the three years of heart surgery data for patient origin.

(d) Step 4. Compute each planning area's average age-specific use rates.

(e) Step 5. Compute each planning area's average age-specific market shares.

(f) Step 6. Multiply the planning area's average age-specific use rates by the area's corresponding forecast year population. The sum of these figures equals the forecasted number of surgeries expected to be performed on the residents of each planning area.

~~((d) Step 4.))~~ (g) Step 7. Apportion the forecasted surgeries among the planning areas in accordance with each area's average age-specific market share for the ~~((last three years of the))~~ four planning areas. This figure equals the forecasted number of state residents' surgeries expected to occur within ~~((the hospitals in))~~ each planning area. In those areas where a newly approved program is being established, an adjustment will be made to reflect anticipated market share shifts consistent with the approved application.

~~((e) Step 5.))~~ (h) Step 8. Increase the number of surgeries expected to occur within ~~((the hospitals in))~~ each planning area in accordance with the percent of surgeries calculated as occurring in ~~((those hospitals))~~ each planning area on out-of-state residents ~~((, based on the average of the last three years))~~. This figure equals the total forecasted number of surgeries expected to occur within ~~((the hospitals in))~~ each planning area.

~~((f) Step 6.))~~ (i) Step 9. Calculate the net need for additional ~~((open))~~ heart surgery ~~((services))~~ programs by subtracting the current capacity from the total forecasted surgeries.

~~((g) Step 7. If the net need is less than the minimum volume standard, no new programs shall be assumed to be needed in the planning area. However, hospitals may be granted certificate of need approval even if the forecasted need is less than the minimum volume standard, provided:))~~ (j) Step 10. The department will not grant a certificate of need to new programs if the net need is less than the minimum volume standard. An exception may be made and a certificate of need granted if (j)(i) and (ii) of this subsection can be met:

(i) The applying hospital can meet all the other certificate of need criteria for ~~((an open))~~ a heart surgery program (including documented evidence of capability of achieving the minimum volume standard); and

(ii) ~~((There is documented evidence that))~~ At least eighty percent of the ~~((patients referred for open))~~ results identified in subsection (6)(b)(iii) of this section for heart surgery ~~((by the medical staff of the applying hospital are referred to institutions))~~ received heart surgery at hospitals more than seventy-five miles away.

~~((5))~~ (8) For the purposes of the forecasting method in this section, the following terms have the following specific meanings:

(a) Age-specific categories. The categories used in computing age-specific values will be fifteen to forty-four year olds, forty-five to sixty-four year olds, sixty-five to seventy-four year olds, and seventy-five and older.

(b) Current capacity. A planning area's current capacity for ~~((open))~~ heart surgeries equals the sum of the highest reported annual volume for each hospital ~~((within the planning area during the most recent available three years data))~~ with an approved heart surgery program within the planning area. In those planning areas where a new program is being established, the assumed volume of that hospital will be the greater of the actual volume or the minimum volume standard or the estimated volume described in the approved application, including any adjustments made by the department in the course of review and approval.

(c) Forecast year. ~~((Open))~~ Heart surgery service needs shall be based on forecasts for the fourth year after the certificate of need ~~((open))~~ heart surgery concurrent review process. ~~((The 1992 reviews will be based on forecasts for 1996.))~~

(d) Market share. The market share of a planning area represents the percent of a planning area's total patient origin adjusted surgeries that were performed in hospitals located in that planning area. ~~((The most recent available three years data will be used to compute the age-specific market shares for each planning area.))~~

(e) ~~((Open))~~ Heart surgeries. ~~((Open))~~ Heart surgeries are defined as diagnosis related groups (DRGs) 104 through ~~((108, inclusive))~~ 111 as developed under the Centers for Medicare and Medicaid Services (CMS)

contract. The department will update the list of codes administratively to reflect future revisions made by CMS to the DRGs to be considered in certificate of need definitions, analyses and decisions. The department's updates to DRGs will be based on the definition of heart surgery contained in subsection (1) of this section. All pediatric surgeries (ages fourteen and under) are excluded.

(f) Out-of-state use of planning area hospitals. The percent of out-of-state use of hospitals within a planning area will equal the percent of total surgeries occurring within the planning area's hospitals that were performed on patients from out-of-state (or on patients whose reported zip codes are invalid). ~~((The most recent available three years data will be used to compute out of state use of planning area hospitals.))~~

(g) Patient origin adjustment. A patient origin adjustment of ~~((open))~~ heart surgeries provides a count of surgeries performed on the residents of a planning area regardless of which planning area the surgeries were performed in. (Surgeries can be patient origin adjusted by using the patient's zip code reported in the CHARS data base.)

(h) Planning areas. Four regional health service areas will be used as planning areas for forecasting ~~((open))~~ heart surgery service needs.

(i) Health service area "one" includes the following counties: Clallam, Island, Jefferson, King, Kitsap, Pierce, San Juan, Snohomish, Skagit, and Whatcom.

(ii) Health service area "two" includes the following counties: Cowlitz, Clark, Grays Harbor, Klickitat, Lewis, Mason, Pacific, Skamania, Thurston, and Wahkiakum.

(iii) Health service area "three" includes the following counties: Benton, Chelan, Douglas, Franklin, Grant, Kittitas, Okanogan, and Yakima.

(iv) Health service area "four" includes Adams, Asotin, Columbia, Ferry, Garfield, Lincoln, Pend Oreille, Stevens, Spokane, Walla Walla, and Whitman.

(v) Use rate. The ~~((open))~~ heart surgery use rate equals the number of surgeries performed on the residents of a planning area divided by the population of that planning area. ~~((The most recent available three years data is used to compute an averaged annual age specific use rate for the residents of each of the four planning areas.))~~

~~((6))~~ (9) The data source for ~~((open))~~ heart surgeries is the comprehensive hospital abstract reporting system (CHARS), office of hospital and patient data, department of health.

~~((7))~~ (10) The data source for population estimates and forecasts is the office of financial management population trends reports.

AMENDATORY SECTION (Amending WSR 96-24-052, filed 11/27/96, effective 12/28/96)

WAC 246-310-262 ((Nonemergent interventional cardiology standard.))
Adult elective coronary interventions--Standards and need forecasting method.

~~((All nonemergent percutaneous transluminal coronary angioplasty (PTCA) procedures and all other nonemergent interventional cardiology procedures are tertiary services as defined in WAC 246-310-010 and shall be performed in institutions which have an established on site open heart surgery program capable of performing emergency open heart surgery.))~~ (1) Adult elective coronary interventions mean catheter-based nonsurgical therapeutic interventions in the heart and great vessels in the chest. These procedures must be provided only in a facility that has on-site inpatient hospital services. For purposes of this section, a facility that has on-site inpatient hospital services includes a permanent structure that is attached to or contiguous with an inpatient hospital facility. These interventions include, but are not limited to: Insertion of coronary artery stents, percutaneous transluminal coronary angioplasty (PTCA), and catheter-based invasive electrophysiologic procedures.

(2) Adult elective coronary interventions are tertiary services as listed in WAC 246-310-020. To be granted a certificate of need, an adult elective coronary intervention program must meet the standards in this section in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.

(3) The department shall review new adult elective coronary intervention services using the concurrent review cycle in this subsection, except as noted in subsection (6) of this section.

(a) Applicants must submit letters of intent between the first working day and last working day of July of each year.

(b) Initial applications must be submitted between the first working day and last working day of August of each year.

(c) The department shall screen initial applications for completeness by the last working day of September of each year.

(d) Responses to screening questions must be submitted by the last working day of October of each year.

(e) The public review and comment period for applications begins on November 16 of each year. If November 16 is not a working day in any year, then the public review and comment period begins on the first working day after November 16.

(f) The public comment period is limited to ninety days, unless extended under WAC 246-310-120 (2)(d). The first sixty days of the public comment period shall be reserved for receiving public comments and conducting a public hearing, if requested. The remaining thirty days shall be for the applicant or applicants to provide rebuttal statements to written or oral statements submitted during the first sixty-day period. Any interested person that:

(i) Is located or resides within the applicant's health service area;
(ii) Testified or submitted evidence at a public hearing; and
(iii) Requested in writing to be informed of the department's decision, must also be provided the opportunity to provide rebuttal statements to written or oral statements submitted during the first sixty-day period.

(g) The final review period may not exceed sixty days, unless extended under WAC 246-310-120 (2)(d).

(4) The department may convert the review of an application that was initially submitted under the concurrent review cycle to a regular review process if the department determines that the application does not compete with another application.

(5) Any letter of intent or certificate of need application submitted for review in advance of this schedule, or certificate of need application under review as of the effective date of this section, shall be held by the department for review according to the schedule in this section.

(6) The department may administratively determine and announce an alternative schedule of the events in subsection (3) of this section, during the first and second year this rule is in force.

(7) Standards.

(a) Hospital volume requirements.

(i) A minimum of two hundred therapeutic catheter-based interventions per year must be performed in hospitals with an adult elective coronary intervention program by the end of the third year of operation and for each year thereafter.

(ii) During the first year of operation, a minimum of one hundred therapeutic catheter-based interventions must be performed.

(b) Hospitals applying for a certificate of need must demonstrate that they can meet one hundred ten percent of the minimum volume standard. The applicant hospital must provide data from CHARS demonstrating:

(i) The zip codes served by the applying hospital;

(ii) The applying hospital's percentage of total adult hospital admissions in the applicable zip codes during the most recent available three years data. Expired patients will not be counted.

(iii) The number of adult therapeutic catheter-based interventions from these zip codes during the most recent available three years data. The percentage established in (b)(ii) of this subsection must then be applied to the number of therapeutic catheter-based interventions. This number must be equal to or greater than two hundred twenty procedures (one hundred ten percent of the minimum volume).

(c) The department will not grant a certificate of need to a new program if the new program would:

(i) Cause the number of procedures at any existing program to drop below two hundred twenty procedures per year; or

(ii) Reduce the number of procedures at any existing program that has not yet reached two hundred twenty procedures per year; or

(iii) Reduce an existing hospital located within fifty miles travel distance that is currently performing in excess of four hundred interventions per year to fewer than four hundred interventions per year.

(d) Physicians performing adult elective coronary interventional procedures at the applying hospital must meet the certification standards in (e) of this subsection and volume standards in (f) of this subsection.

(e) Physician certification standards.

(i) Director of interventional cardiology. At the time the project is initiated, and thereafter, the director of the adult elective coronary intervention program must be U.S. board certified in general cardiology and become U.S. board certified in interventional cardiology within two years.

(ii) Established cardiologists. Established cardiologists are defined as cardiologists out of fellowship for more than two years as of the effective date of this section. At the time of project commencement, and thereafter, established cardiologists must be U.S. board certified or board prepared in interventional cardiology. Board prepared status must not extend beyond five years. Cardiologists certified in general cardiology at time of project commencement and thereafter, must be U.S. Interventional Cardiology Board certified within five years.

(iii) New cardiologists. New cardiologists means those cardiologists out of fellowship for less than two years. At the time of project

commencement, and thereafter, new cardiologists must be U.S. board certified or board prepared in interventional cardiology and must maintain certification. Board prepared status must not extend beyond two years.

(iv) An exception to the requirement for interventional cardiology board certification or prepared for both (e)(i) and (ii) of this subsection applies to physicians having acquired board certification in cardiology prior to 2003 and having acquired documented personal post-training experience of at least five hundred interventions or at least one hundred fifty post-training interventions in the preceding two years.

(f) Physicians volume standard.

(i) Established cardiologists. Established cardiologists (including the director of interventional cardiology) must perform a minimum of seventy-five catheter-based therapeutic interventions per year. An exception to this volume standard is given to those established cardiologists who have performed a minimum of five hundred post-training cases during his/her career. For these established cardiologists the minimum volume standard is fifty procedures per year.

(ii) New cardiologists. New cardiologists must perform a minimum of fifty catheter-based therapeutic interventions per year until they have been in post-fellowship practice for two years. After the two-year period, these cardiologists must meet the established cardiologist minimum volume standards.

(g) Hospitals with adult elective coronary intervention programs must have plans for facilitating safe and swift emergency access to heart surgery services at all times for the population they serve. These plans must include, at a minimum:

(i) A formal written transfer agreement for emergency medical/surgical management with at least one hospital that provides heart surgery services, that can be reached expeditiously from the program by available emergency transport within a reasonable amount of time (never to exceed two hours) and that provides the greatest assurance of patient safety;

(ii) A plan for conferences between representatives from the heart surgery program(s) and the elective coronary intervention program to be held at least quarterly, in which a significant number of preoperative and post-operative cases are reviewed, including all transport cases;

(iii) Arrangements for addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.); and

(iv) The maintenance of, or affiliation with, emergency transportation services (including contingency plans for poor weather and known traffic congestion problems).

(h) Hospitals with adult elective coronary intervention programs must provide a copy of the hospital's QI plan that includes/incorporates a section specific to the adult elective coronary intervention program.

(i) If a certificate of need is issued, it will be conditioned, at a minimum, to require ongoing compliance with the certificate of need standards. Failure to meet the conditioned standards may be grounds for revocation or suspension of a hospital's certificate of need, or other appropriate licensing or certification actions.

(j) If two or more hospitals are competing to meet the same forecasted net need, the department shall consider the following factors when determining which proposal best meets forecasted need:

(i) The most appropriate improvement in geographic access;

(ii) The most cost efficient service;

(iii) Minimizing impact on existing adult coronary intervention programs;

(iv) Providing the greatest breadth and depth of cardiovascular and support services; and

(v) Facilitating emergency access to care.

(k) Hospitals granted a certificate of need have three years from the date of initiating the program to meet the program procedure volume standards.

(l) These standards should be reevaluated every three years.

(8) Need forecasting method. The data used for evaluating applications submitted during the concurrent review cycle will be the most recent three years CHARS data available at the close of the application submittal period for that review cycle.

(a) Step 1. Compute the planning area's current capacity. In those planning areas where a new program has operated less than three years, the assumed volume of that hospital will be the greater of the actual volume or the minimum volume standard or the estimated volume described in the approved application, including any adjustments made by the department in the course of review and approval.

(b) Step 2. Adjust the data for patient origin.

(c) Step 3. Compute the average percent of out-of-state use of each planning area. This is calculated by dividing the number of catheter-based therapeutic interventions occurring within the planning area's hospitals that were performed on residents from out-of-state (or on patients whose reported zip codes are invalid) by the sum of interventions performed on residents of that planning area and out-of-state residents.

(d) Step 4. Compute each planning area's average age-specific use rates.

(e) Step 5. Multiply the planning area's average age-specific use rates by the area's corresponding forecast year population. The sum of these figures equals the forecasted number of catheter-based therapeutic interventions expected to be performed on the residents of each planning area.

(f) Step 6. For each planning area, increase the number of projected catheter-based therapeutic interventions in accordance with the percent of catheter-based therapeutic interventions projected for out-of-state residents.

(g) Step 7. Calculate the net need for additional adult elective coronary intervention programs by subtracting the current capacity from the results of step 6.

(h) Step 8. The department will not grant a certificate of need for new programs if the net need is less than the minimum volume standard. An exception may be made and a certificate of need granted if (h)(i) and either (ii) or (iii) of this subsection can be met:

(i) The applying hospital meets all the other certificate of need criteria for an adult elective coronary intervention program (including documented evidence of capability of achieving the minimum volume standard); and

(ii) There is no existing program in the planning area; or

(iii) If there is an existing program in the planning area, eighty percent of the results identified in subsection (7)(b)(iii) of this section for catheter-based therapeutic interventions received interventional services at hospitals more than seventy-five miles away.

(9) For the purposes of the forecasting method in this section, the following terms have the following specific meanings:

(a) Age-specific categories. The categories used in computing age-specific values will be fifteen to forty-four year olds, forty-five to sixty-four year olds, sixty-five to seventy-four year olds, and seventy-five and older.

(b) Current capacity. A planning area's current capacity for adult elective coronary interventions equals the sum of the highest reported annual volume for each hospital with an approved adult interventional program or a department grandfathered program within the planning area. In those planning areas where a new program has operated less than three years, the assumed

volume of that hospital will be the greater of the actual volume or the minimum volume standard or the estimated volume described in the approved application, including any adjustments made by the department in the course of review and approval.

(c) Forecast year. Adult elective coronary intervention service needs must be based on forecasts for the fourth year after the certificate of need adult elective coronary intervention concurrent review process.

(d) Adult elective coronary interventions. Adult elective coronary interventions means diagnosis related groups as developed under the Centers for Medicare and Medicaid Services (CMS) contract that describe catheter-based interventions involving the coronary arteries and great arteries of the chest. All pediatric catheter-based therapeutic and diagnostic interventions (ages fourteen and under) are excluded. The department will update the list of codes administratively to reflect future revisions made by CMS to the DRGs to be considered in certificate of need definitions, analyses, and decisions. The department's updates to DRGs will be based on the definition of adult elective coronary interventions contained in WAC 246-310-262(1).

(e) Patient origin adjustment. A patient origin adjustment of catheter-based therapeutic interventions provides a count of interventions performed on the residents of a planning area regardless of which planning area the interventions were performed in. (Interventions can be patient origin adjusted by using the patient's zip code reported in the CHARS data base.)

(f) Planning areas. Planning area means each individual county designated by the department as the smallest geographic area for which adult coronary interventions are projected.

(g) Use rate. The adult elective coronary intervention use rate equals the number of catheter-based therapeutic interventions performed on the residents of a planning area divided by the population of that planning area.

(h) Grandfathered programs means those hospitals operating a certificate of need approved interventional cardiac catheterization program or heart surgery program prior to the effective date of these rules. For hospitals with jointly operated programs, only the hospital where the program's procedures were approved to be performed will be grandfathered.

(10) The data source for adult elective coronary interventions is the comprehensive hospital abstract reporting system (CHARS), office of hospital and patient data, department of health.

(11) The data source for population estimates and forecasts is the office of financial management population trends reports.

NEW SECTION

WAC 246-310-263 Pediatric cardiac surgery and interventional treatment center standards and need forecasting method. (1) A pediatric cardiac surgery and interventional treatment center is a hospital providing comprehensive pediatric cardiology care, including medical and surgical diagnosis and treatment.

(2) Pediatric cardiac surgery and interventions includes, but is not limited to: All pediatric surgery of the heart (excluding organ transplantation) and the great vessels in the chest; all pediatric catheter-based nonsurgical therapeutic and diagnostic interventions in the heart and great vessels in the chest; and invasive pediatric electrophysiologic procedures.

(3) Pediatric cardiac surgery and interventional procedure is a

tertiary service as listed in WAC 246-310-020. To be granted a certificate of need for a pediatric cardiac surgery and interventional treatment center, a hospital must meet the standards in this section in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.

(4) The department must review new pediatric cardiac surgery and interventional center applications using the concurrent review cycle in this section.

(a) Applicants must submit letters of intent between the first working day and last working day of August of each year.

(b) Initial applications must be submitted between the first working day and last working day of September of each year.

(c) The department shall screen initial applications for completeness by the last working day of October of each year.

(d) Responses to screening questions must be submitted by the last working day of November of each year.

(e) The public review and comment period for applications begins on December 16 of each year. If December 16 is not a working day in any year, then the public review and comment period begins on the first working day after December 16.

(f) The public comment period is limited to ninety days, unless extended according to the provisions of WAC 246-310-120 (2)(d). The first sixty days of the public comment period shall be reserved for receiving public comments and conducting a public hearing, if requested. The remaining thirty days shall be for the applicant or applicants to provide rebuttal statements to written or oral statements submitted during the first sixty-day period. Any interested person that:

(i) Is located or resides within the applicant's health service area;

(ii) Testified or submitted evidence at a public hearing; and

(iii) Requested in writing to be informed of the department's decision, must also be provided the opportunity to provide rebuttal statements to written or oral statements submitted during the first sixty-day period.

(g) The final review period is limited to sixty days, unless extended according to the provisions of WAC 246-310-120.

(5) The department may convert the review of an application that was initially submitted under the concurrent review cycle to a regular review process if the department determines that the application does not compete with another application.

(6) Any letter of intent or certificate of need application submitted for review in advance of this schedule, or certificate of need application under review as of the effective date of this section, shall be held by the department for review according to the schedule in this section.

(7) Standards.

(a) A minimum of one hundred pediatric cardiac surgical procedures (seventy-five with extracorporeal circulation) per year and a minimum of one hundred fifty catheterizations must be performed at a hospital with a pediatric cardiac surgery and interventional treatment center by the third year of operation and each year thereafter.

(b) Hospitals applying for a pediatric cardiac surgery and interventional center certificate of need must demonstrate that they can meet one hundred ten percent of the minimum volume standards. The applicant hospital must provide data from CHARS demonstrating:

(i) The zip codes served by the applying hospital;

(ii) The percentage of the total hospital admissions for children ages zero through nineteen served by the applying hospital in each of the applicable zip codes during the most recent available three years data. Expired patients will not be counted;

(iii) The number of pediatric heart surgeries, number of therapeutic and diagnostic interventions and invasive electrophysiologic procedures

performed in these zip codes during the most recent available three years data. The percentage established in (b)(ii) of this subsection shall then be applied to the number of pediatric heart surgeries, interventions and invasive electrophysiologic procedures. This number must be equal to or greater than one hundred ten percent of the minimum volume standards.

(c) The department will not grant a certificate of need to a new center if:

(i) The new center will reduce any existing center below one hundred ten percent of any one of the minimum volume standards; or

(ii) Reduces the volumes of any existing center that has not yet met any one of the minimum volume standards; or

(iii) Fails to meet any one of the center's minimum volume standards.

(d) At time of initiating the program, and thereafter, the director of the pediatric cardiac surgery and interventional center must be a U.S. board certified pediatric cardiologist.

(e) At time of initiating the program, and thereafter, pediatric cardiac surgery and interventional centers must have at least two U.S. board certified or board prepared cardiac surgeons on the staff. At least one of the required surgeons must be certified by the American Board of Thoracic Surgery. Board prepared status must not extend beyond five years.

(f) The program must provide twenty-four hour coverage.

(g) Hospitals with a pediatric cardiac surgery and interventional center must have plans for facilitating emergency access to heart surgery services at all times for the population they serve. These plans should, at minimum, include arrangements for addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.), and the maintenance of or affiliation with emergency transportation services (including contingency plans for poor weather and known traffic congestion problems).

(h) Hospitals with a pediatric cardiology surgery and interventional center must provide a copy of the hospital's QI plan that includes/incorporates a section specific to the pediatric cardiac surgery and interventional center.

(i) If a certificate of need is issued, it will be conditioned, at a minimum, to require ongoing compliance with the certificate of need standards. Failure to meet the conditioned standards may be grounds for revocation or suspension of a hospital's certificate of need, or other appropriate licensing or certification action.

(j) In the event two or more centers are competing to meet the same forecasted net need, the department shall consider the following factors when determining which proposal best meets forecasted need:

(i) The most appropriate improvement in geographic access;

(ii) The most cost efficient service;

(iii) Minimizing impact on existing programs;

(iv) Providing the greatest breadth and depth of pediatric cardiovascular and support services; and

(v) Facilitating emergency access to care.

(k) Hospitals granted a certificate of need have three years from the date of initiating the program to meet the center procedure volume standards.

(l) These standards should be reevaluated every three years.

(8) Need forecasting method. The data used for evaluating applications submitted during the concurrent review cycle will be the most recent three years CHARS data available at the close of the application submittal period for that review cycle. Separate forecasts are to be made for heart surgery, interventions and electrophysiological procedures.

(a) Step 1. Compute the planning area's current capacity. When a new center is being established, the assumed volume of that center will be the greater of the actual volume or the minimum volume standards or the estimated volumes described in the approved application, including any adjustments made

by the department in the course of review and approval.

(b) Step 2. Compute the percent of out-of-state use of the area's hospitals.

(c) Step 3. Compute the planning area's average age-specific use rates.

(d) Step 4. Multiply the planning area's age-specific use rates by the area's corresponding forecast year population. The sum of these figures equals the forecasted number of pediatric cardiac surgical and interventional procedures expected to be performed on Washington pediatric residents.

(e) Step 5. Increase the number of pediatric cardiac surgical and interventional procedures expected to occur within the planning area in accordance with the percent of procedures calculated as occurring in those hospitals on out-of-state residents, based on the average of the last three years. This figure equals the total forecasted number of procedures expected to occur within the hospital's planning area.

(f) Step 6. Calculate the net need for additional pediatric cardiac centers by subtracting the current capacity from the total forecasted pediatric cardiac surgical and interventional procedures.

(g) Step 7. The department will not grant a certificate of need for a new center if the need is less than the minimum volume standards. An exception may be made and a certificate of need granted if (g)(i) and (ii) of this subsection can be met:

(i) The applying hospital can meet all the other certificate of need criteria for a pediatric cardiac surgery and interventional treatment center (including documented evidence of capability of achieving the minimum volume standard); and

(ii) At least eighty percent of the results identified in subsection (7)(b)(iii) of this section for pediatric cardiac services received pediatric cardiac services more than seventy-five miles away.

(9) For the purposes of the forecasting method in this section, the following terms have the following specific meanings:

(a) Age-specific categories. The categories used in computing age-specific values will be zero through fourteen, fifteen through nineteen year olds.

(b) Current capacity. The planning area's current capacity for pediatric cardiac surgical and interventional procedures equals the sum of the highest reported annual volume for each hospital with an approved pediatric cardiac surgical and interventional center within the planning area. When a new center is being established, the assumed volumes of that center will be the greater of the actual volume or minimum volume standards or the estimated volumes described in the approved application, including any adjustments made by the department in the course of review and approval.

(c) Forecast year. Pediatric cardiac surgery and interventional service needs shall be based on forecasts for the fourth year after the certificate of need pediatric cardiac surgery and interventional concurrent review process.

(d) Pediatric cardiac surgery and intervention. Pediatric cardiac surgery and intervention means diagnosis related groups (DRGs) 104-111 and 115-116, as developed under the Centers for Medicare and Medicaid Services (CMS) contract. All adult cardiac procedures (ages twenty-one and over) are excluded. The department will update the list of codes administratively to reflect future revisions made by CMS to the DRGs to be considered in certificate of need definitions, analyses and decisions. The department's updates to DRGs will be based on the definition of pediatric heart surgery contained in subsection (2) of this section.

(e) Out-of-state use of planning area hospitals. The percent of out-of-state use of hospitals within the planning area will equal the percent of total pediatric cardiac surgery and interventional procedures occurring within the planning area's hospitals that were performed on patients from

out-of-state (or on patients whose reported zip codes are invalid). The most recent available three years data will be used to compute out-of-state use of Washington hospitals.

(f) Planning area. For the purpose of pediatric cardiac surgery and intervention, the planning area is the state of Washington.

Use rate. The pediatric cardiac surgery and interventional use rate equals the number of procedures performed on the pediatric residents of the planning area.

(10) The data source for pediatric cardiac surgery and interventional procedures is the comprehensive hospital abstract reporting system (CHARS), office of hospital and patient data, department of health.









(11) The data source for population estimates and forecasts is the office of financial management population trends reports.


AMENDATORY SECTION (Amending WSR 03-22-020, filed 10/27/03, effective 11/27/03)

WAC 246-310-990 Certificate of need review fees. (1) An application for a certificate of need under chapter 246-310 WAC must include payment of a fee consisting of the following:

(a) A review fee based on the facility/project type;

(b) If more than one facility/project type applies to an application, the review fee for each type of facility/project must be included.

Facility/Project Type	Review Fee
Ambulatory Surgical Centers/Facilities	\$13,379.00
Amendments to Issued Certificates of Need	\$8,432.00
Emergency Review	\$5,427.00
Exemption Requests	
 Continuing Care Retirement Communities (CCRCs)/Health Maintenance Organization (HMOs)	\$5,427.00
 Bed Banking/Conversions	\$883.00
 Determinations of Nonreviewability	\$1,261.00
 Hospice Care Center	\$1,136.00
 Nursing Home Replacement/Renovation Authorizations	\$1,136.00
 Nursing Home Capital Threshold under RCW 70.38.105 (4)(e) (Excluding Replacement/Renovation Authorizations)	\$1,136.00
 Rural Hospital/Rural Health Care Facility	\$1,136.00
Extensions	
 Bed Banking	\$505.00

 Certificate of Need/Replacement Renovation Authorization Validity Period	\$505.00
Home Health Agency	\$16,155.00
Hospice Agency	\$14,388.00
Hospice Care Centers	\$8,432.00
Hospital (Excluding Transitional Care Units-TCUs, Ambulatory Surgical Center/Facilities, Home Health, Hospice, and Kidney Disease Treatment Centers)	\$26,506.00
Kidney Disease Treatment Centers	\$16,409.00
Nursing Homes (Including CCRCs and TCUs)	\$30,293.00

(2) The fee for amending a pending certificate of need application is determined as follows:

(a) If an amendment to a pending certificate of need application results in the addition of one or more facility/project types, the review fee for each additional facility/project type must accompany the amendment application;

(b) If an amendment to a pending certificate of need application results in the removal of one or more facility/project types, the department shall refund to the applicant the difference between the review fee previously paid and the review fee applicable to the new facility/project type; or

(c) If an amendment to a pending certificate of need application results in any other change as identified in WAC 246-310-100, a fee of one thousand three hundred fifty-one dollars must accompany the amendment application.

(3) Where a hospital simultaneously submits applications for heart surgery and elective coronary interventions certificates of need, as required by WAC 246-310-261(2), the combined fee for the two applications will be one hundred fifty percent of the normally required sum for one application.

(4) If a certificate of need application is returned by the department under WAC 246-310-090 (2)(b) or (e), the department shall refund seventy-five percent of the review fees paid.

~~((4))~~ (5) If an applicant submits a written request to withdraw a certificate of need application before the beginning of review, the department shall refund seventy-five percent of the review fees paid by the applicant.

~~((5))~~ (6) If an applicant submits a written request to withdraw a certificate of need application after the beginning of review, but before the beginning of the ex parte period, the department shall refund one-half of all review fees paid.

~~((6))~~ (7) If an applicant submits a written request to withdraw a certificate of need application after the beginning of the ex parte period the department shall not refund any of the review fees paid.

~~((7))~~ (8) Review fees for exemptions and extensions are nonrefundable.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 246-310-132

Open heart surgery concurrent review cycle.